REMARKS/ARGUMENTS

In the specification, the paragraphs beginning at page 9, line 22 has been amended to correct minor editorial problems. The word "survival" has been added after the word "enhanced" to cure a minor omission. This is not considered to be new matter, as the concept is pervasive throughout the disclosure, and is suggested by the surrounding text of the paragraph in question.

Claims 1-13 remain in this application.

Claims 4 and 9-13 have been withdrawn as the result of an earlier restriction requirement..

Claims 1-3 and 5-8 are under consideration.

In view of the examiner's earlier restriction requirement, applicant retains the right to present claims 4 and 9-13 in a divisional application.

In response to the Office Action of **November 2, 2006**, Applicant requests re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Rejections under 35 USC 112

Claims 1-3, *5-8,* 15, and 16 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims

1-3, 5-8, 15, and 16 are alleged to be indefinite because claim 1 recites the phrase "identifying characteristics".

Claim 8 is further alleged to be indefinite because it recites the phrase a "chimerized antibody". The Examiner indicates that the exact meaning of the word chimera is not known, and that the term chimera is generic to a class of antibodies which are products of genetic shuffling of antibody domains and other active proteins. The Examiner further indicates that the term encompasses antibodies fused to non-immunoglobulin proteins as well as antibodies wherein any domain of the antibody is substituted by corresponding regions or residues of human antibodies including but not limited to CDR grafted antibodies. Thus it is the Examiner's position that the metes and bounds of the claim protection sought cannot be determined.

Accordingly, the claims have been amended to remove the phrase "identifying characteristics" and have been amended to recite "the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-5643".

This language is believed to succinctly and specifically claim the specific isolated monoclonal antibody produced from the hybridoma deposited with the ATCC as accession number PTA-5643.

Basis for this amendment may be found in the specification at page 15, lines 5-13.

Claim 8 has been amended to recite:

"The method of claim 1 wherein said antibody is a chimeric antibody produced from the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-5643."

Basis for this amendment may be found at page 7, lines 4-21, and page 13 lines 12-18 of the specification as originally filed. The metes and bounds of the claim now specifically relate to chimeric antibodies produced from the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-4890.

Claims 1-3, 5-8, 15 and 16 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of extending survival by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics which is encoded by a clone deposited with the ATCC as accession number PTA-5643 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby survival is extended,

does not reasonably provide enablement for a method of extending survival and/or delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the *identifying characteristics* of a monoclonal antibody encoded by a clone deposited with the ATCC accession number PTA-5643 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and/or survival is extended. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Accordingly, all of the claims have been amended to remove the phrase "identifying characteristics" and have been amended to recite that the antibody recited in the claims is limited to "the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-5643", or to humanized or chimeric antibodies "produced from the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-5643".

Furthermore, claims 15 and 16 have been cancelled and claim 1 has been limited to treatment of human breast and ovarian tumors.

Regarding the Examiner's comments regarding use of body weight as a surrogate marker of disease progression are respectfully disagreed with. With reference to the specification at page 10, lines 2-9, page 17, lines 8-22, the specification teaches use of body weight as a surrogate marker of disease progression in a xenograft model of ovarian cancer in SCID mice, and further goes on to indicate a reduction of tumor burden in both breast and ovarian tumors as a result of treatment with the instant PTA-5643 antibody. It is improper to limit the claims to a specific exemplary embodiment. The claims are drawn to treatment of a human tumor wherein the tumor expresses an antigen which specifically binds to the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-5643. Further, the rejection on the basis of alleged failure to treat metastatic disease is not understood. Firstly, all cancers do not metastasize. Secondly, the demonstration that tumor burden is reduced or reversed by treatment with the claimed antibody, and that weight loss is prevented, is indicative of a delay in disease progression, and

is evidence, in and of itself, of a delay in disease progression.

It is respectfully submitted that a valid model could be easily developed for any cancer expressing such an antigen to codify reduction of body weight as a surrogate marker of disease progression, and for this and the reasons stated above, the rejection should therefore be withdrawn and the claims passed to issue.

Claims 1-3,5,6,8 and 15-16 further stand rejected under 35 USC 112 as being drawn to the treatment of a human tumor in a human using a mouse antibody. The Examiner indicates that such treatment could not be predicted to be successful, e.g. due to development of a HAMA response.

Applicant respectfully disagrees with the Examiner's conclusions. Numerous references exist in the literature regarding the utility of the murine antibody mAb 4D5 for the treatment of human tumors, notably human breast cancers. Therefore, based on demonstrable success with mouse monoclonals against human tumors, it is reasonable to predict that non-humanized antibodies will be useful in the treatment of human tumors, particularly as a HAMA response is certainly not immediate, and may, in fact, not occur to an extent which will negate the demonstrated utility of the mouse antibody. It is

therefore respectfully requested that this ground of rejection be withdrawn.

Claim 5, drawn to the method of claim 1 wherein said antibody mediates antibody dependent cellular cytotoxicity, stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of claim 1 wherein said antibody mediates antibody dependent cellular cytotoxicity, wherein the monoclonal antibody which has the identifying characteristics of a PTA-5643 is of the murine immunoglobulin subclass IgG2A or IgG3 or humanized with human immunoglobulin subclass IgGI or IgG3, is alleged to not reasonably provide enablement for the method of claim 1 wherein said antibody mediates antibody dependent cellular cytotoxicity. The specification is also alleged to not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Accordingly, the claims have been amended to remove the phrase "identifying characteristics" and the phrase "antibody dependent" so that the claim now states "The method of claim 1 wherein said antibody mediates cellular cytotoxicity".

Antibody mediation of cellular cytotoxicity, per se, finds ample basis in the disclosure, for example at page 11, lines 5 - page 12, line 2, and at page 13, line 19 - page 14, line 1.

The claim, as amended, thus should be understood to include any form of antibody mediation of cellular cytotoxicity related to antibodies produced from the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-5643.

Regarding the rejection of claim 1-3,5-8,15 and 16 of paragraph 11 of the Office action, it is respectfully submitted that removal of the phrase "identifying characteristics" and limitation of the claims to antibodies produced from the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-5643, as described *supra*, obviates this ground of rejection.

Likewise, the rejection of claim 1,6,7,8and 15 under 35 USC 102(b) over Cobleigh et al and the rejection of claims 2 and 3 under 35 USC 103(a) over Cobleigh et al in view of Dillman is obviated by removal of the phrase "identifying characteristics" and limitation of the claims to antibodies produced from the isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-5643, as described *supra*.

With respect to the provisional double patenting rejections in paragraphs 15 and 16 of the Office action, it is respectfully submitted that removal of the phrase "identifying characteristics" and limitation of the claims to antibodies produced from the

isolated monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-5643, as described *supra*, obviates this ground of rejection.

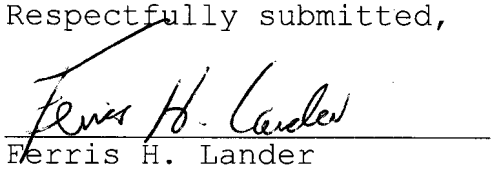
Given that a "nonstatutory" double patenting rejection may still exist, a Terminal Disclaimer is being filed herewith for copending applications 10/949,846; 10/810,744; and 11/370,255.

It is believed that submission of these Terminal Disclaimers obviates any possible provisional non-statutory double patenting rejections.

SUMMARY

In light of the foregoing remarks and amendment to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,



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